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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,878	12/10/2003	Jean-Philippe Girard	BIOBANK.012A	8136

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/733,878	GIRARD ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-80 and 111-139* is/are pending in the application.

4a) Of the above claim(s) *5,6,8-18,20-80 and 111-139* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of July 31, 2006 on January 31, 2007.

Applicant indicates that an amendment filed July 7, 2004 indicates that claims 83-110, 140-212 are cancelled (Applicant's response, page 12). The Examiner acknowledges that an amendment has been filed canceling these claims.

Claims 2, 81-110, 140-212 are cancelled. This application contains claims 5, 6, 8, 18, 20, 80, 111-139 drawn to an invention nonelected with traverse in the reply filed on May 22, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1, 3, 19 are amended.

Claims 1, 3, 4, 7, 19 are under consideration.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on January 31, 2007. It is noted that the references cited on the IDS, January 31, 2007, lists references that had not been considered previously. These references have been considered.

Withdrawn Objections

Drawings

Applicant's arguments, see page 13, Applicant's response, filed January 31, 2007, with respect to the objection to the Drawings have been fully considered and are

persuasive. Applicant indicates that new drawings have been submitted. The objection to the drawings has been withdrawn.

Specification and Sequence Listing

Applicant's arguments, see page 13, Applicant's response, filed January 31, 2007, with respect to the objection to the specification have been fully considered and are persuasive. Applicant indicates that the Brief Description of the Drawings indicates indicate that SEQ ID NOs. have been assigned to the sequences of Figures 18A and 18B. The objection to the sequences has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 7, 19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record, July 31, 2006.

Applicant's arguments filed January 31, 2007 have been fully considered but they are not persuasive.

Applicant indicates that Tables 3A and 3B lists at least 120 genes, which have their expression modulated in response to THAP1 bound to SLC (Applicant's response, page 14, 3rd parag.). In response, this is not persuasive because the example is not germane to the instant invention as THAP1 is a different complex than THAP1/SLC. Also note that THAP1/SLC is a different invention (see claims 20, 22), which was not elected. As such, the publication by Kloosterboer et al. is not germane to the discussion. Applicant indicates that page 321, lines 1-27 and Table 2A show that survivin and HMMR are modulated in response to THAP1 alone (Applicant's response, page 14, 3rd parag.). In response, this is not persuasive. With regard to survivin, Example 45, Table 2A, demonstrates that survivin is downregulated in endothelial cells. It is not clear how to extrapolate any inflammation disease from endothelial cells without further guidance. The publication provided by Applicant, Altznauer et al., 2004, is post-filing art and teaches survivin expression in lymphocytes. Because Altznauer et al., is post-filing art, an artisan cannot rely upon it as providing an enabling disclosure for the claimed invention. In addition to this, it is not readily apparent how the teaching in endothelial cells in the specification can be extrapolated from lymphocytes taught by Altznauer et al. It is also not clear how one extrapolates that THAP regulates survivin in lymphocytes, such that the claimed invention could be practiced at the time of filing. It should be made clear at this time that the rejection that was being made (Office Action, July 31, 2006, pages 10-11) was that neither the specification nor the art provide any guidance as to what structural/functional features a peptide involved in immune disease

(claim 19) has such that it was clear that an artisan was in possession of the genus of polypeptides involved in inflammatory disease . Thus, the rejection remains.

Applicant indicates that the Examiner alleges that the specification does not teach whether any THAP protein has a transcriptional repressor or activator such that an artisan could use THAP or any biologically active fragment thereof and monitor transcriptional activity. Applicant indicates that claim 1 has been amended to, "a THAP1 polypeptide or a biologically active fragment thereof." Examples 39, 45, and 47 provide support for the involvement of THAP1 in transcriptional modulation (Applicant's response, page 14, 4th parag.). In response, this is not persuasive. The issue at hand with regard to this rejection is that the specification provides no guidance as to what characteristic(s) a "biologically active fragment" of THAP1 is, such that an artisan could identify it. More particularly, as the method is a method involving transcriptional repression of a THAP1 responsive gene, the specification does not provide guidance as to what part(s) of THAP1 control transcriptional repression of a THAP1 responsive gene. Thus, the rejection remains.

Applicant indicates that the Examiner alleges that the specification does not enable an artisan to expect that several conserved amino acids amongst proteins would necessarily have the same structure and biological activity between proteins (Applicant's response, page 15, 2nd parag.). In response, Applicant is reminded that this is a Written Description rejection and the issue that arises from this rejection is that the specification does not indicate that the Applicant was in possession of the genus of THAP1 proteins. Applicant indicates that it is a well known fact that proteins having

conserved domains have the same biological function (for example, the heme-binding domain of hemoglobin and myoglobin, the catalytic triad of serine proteases, etc.). Applicant indicates that claim 1 has been amended to relate to, "a THAP1 polypeptide or biologically active fragment thereof." Examples 39, 45, and 47 provide support for the involvement of THAP1 in transcriptional modulation (Applicant's response, page 15, 2nd parag.). In response, this is not persuasive. The issue that the Examiner was indicating was that the specification does not provide any guidance what biological function the amino acids of 1-89 of THAP1 has, such that an artisan would know that specific residues in amino acids 1-89 of THAP1 is what comprises a site-specific DNA binding domain. It is noted that while Applicant has amended the claims (e.g. claim 1) from "THAP family" to "THAP1," the amendment does not overcome the rejection at hand as the claim is now readable on THAP1 from other species of animals. Because it is unclear what amino acids or structure is required for THAP1 binding to a particular region of DNA, the rejection remains.

The rejection of claim 2 is withdrawn as the claim is cancelled. It is noted that claim 5 was inadvertently included in the rejection, July 31, 2006. However, per restriction requirement, July 31, 2006, claim 5 was withdrawn.

Claims 1, 3, 4, 7, 19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed January 31, 2007 have been fully considered but they are not persuasive.

Applicant indicates that to practice the claimed invention as set forth in claim 1, a skilled artisan does not need to know whether transcription modulation is by direct activation or repression or whether it occurs indirectly, for example, by initiation of a signal transduction cascade (Applicant's response, page 15, 2nd parag. under "Rejection of claims 1-4, 7, 19 under 35 U.S.C. § 112, first paragraph (enablement)" to page 16, 1st parag.). In response, while it is clear that claim 1 is drawn to a method of THAP1 repressing a THAP1 responsive gene (i.e. direct regulation of a THAP1 responsive gene), the specification does not provide guidance that THAP1 is responsible for regulating the genes listed in Example 45, Table 2A. Note that Table 2A only indicates that genes were downregulated following administration of THAP1 to endothelial cells; it does not indicate whether any of the genes are directly regulated by THAP1, such that the claims can be practiced without undue experimentation. As such, the specification does not provide sufficient guidance that the claims are enabled for a method of modulating interaction of THAP1 polypeptide with a nucleic acid.

Applicant indicates that claim 3, which depends from claim 1, states that the nucleic acid is a THAP-responsive promoter. Claim 4 states that the THAP-responsive promoter comprises a THAP responsive element. THAP responsive promoter and THAP responsive elements are defined in the specification, page 148, line 13 to page

150, line 2 (Applicant's response, page 16, 3rd parag.). Applicant indicates that Example 46 describes the localization of a DR5-type element in the survivin gene and a THRE element in the USP16 gene (Applicant's response, page 18). In response, Example 46 indicates that putative binding sites were found; however, this does not provide guidance that these sites are bound by THAP1 and that the binding of THAP1 represses expression of the THAP1 responsive genes, as other cellular factors could be responsible for the repression of the gene. Further, it is noted that this also does not provide guidance that biologically active fragments of THAP1 repress expression of THAP1 responsive genes.

Applicant indicates that claim 7, which depends from claim 4, states that the THAP-responsive element is THRE (Applicant's response, page 18, 2nd parag. following the citation from the specification). As discussed above in connection with claims 3 and 4, the specification provides an example of a THAP-modulated gene having a THRE element. In response, this is not persuasive. As indicated in the previous paragraph, finding putative THRE binding sites is not indicative that THAP1 binds the site. The results described in Example 45 could include genes that are indirectly regulated by THAP1. As such, the claimed invention cannot be practiced.

Applicant indicates that the specification does not lack enablement for the use of ay THAP-family polypeptide. However, this aspect of the rejection has been sufficiently addressed by the amendment to claim 1 (Applicant's response, page 19, 2nd parag.). In response, as indicated above in the Written Description rejection, the specification does not provide guidance for an artisan to arrive at the claimed invention. It is unclear what

structure(s) of THAP1 is required such that an artisan could obtain a fragment of THAP1 that represses a THAP1 responsive gene. As such, the amendment to claim 1 is not persuasive.

The rejection of claim 2 is withdrawn as the claim is cancelled. It is noted that claim 5 was inadvertently included in the rejection, July 31, 2006. However, per restriction requirement, July 31, 2006, claim 5 was withdrawn.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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PRIMARY EXAMINER